Hemocue Urine Albumin Point-Of-Care Test Shows Strong Agreement With the Results Obtained With a Large Nephelometer

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There is an increasing incidence of diabetic nephropathy, predominantly in patients with type 2 diabetes (1–3). Persistent microalbuminuria is a sign of ongoing glomerular injury and a strong predictor of clinical nephropathy, and screening for microalbuminuria, the earliest manifestation of diabetic nephropathy, is recommended for all diabetic patients (4).

Point-of-care testing (POCT) offers rapid test results, which facilitate the use of the results to motivate the patient to lifestyle changes and increased compliance (5–7). To achieve good compliance, it is essential that the patient and physician work together and that the patient get regular feedback on the treatment results. The feedback is considered to be more effective if the test results are available during the consultation. This has led to the development of POCT instruments for measuring urine albumin excretion.

The aim of the present study was to evaluate urine albumin analyzed by the HemoCue POCT instrument, which can provide rapid test results, in relation to urine albumin analyzed by a central laboratory instrument (ProSpec) and the albumin-to-creatinine ratio (ACR) in a group of elderly men.

RESEARCH DESIGN AND METHODS

— This study is a cross-sectional investigation of Swedish men, 77 years of age, who were participants in Uppsala Longitudinal Study of Adult Men (8). The study was approved by the ethics committee at Uppsala University. A total of 706 (103 individuals with type 2 diabetes) 24-h urine samples were analyzed.

Urine albumin

Urine albumin was analyzed with HemoCue Urine Albumin (HemoCue, Ängelholm, Sweden) and Behring BN ProSpec (Dade Behring, Deerfield, IL) analyzers. The HemoCue instrument had a measuring range of 10–150 mg/l. Urine creatinine was analyzed with a modified kinetic Jaffe reaction on an Architect Ci8200 analyzer (Abbott, Abbot Park, IL) and reported as SI units (micromoles per liter), and ACR was calculated from the Prospec results.

Statistical calculations

For the statistical analysis, urine albumin values below the detection limits were assigned the value of the detection limit. All calculations were performed with Statistica 4.5 (StatSoft, Tulsa, OK). Associations between variables were tested with Spearman's rank correlation analysis.

RESULTS

Correlation between urine albumin and ACR assays

There was a strong correlation between duplicate tests ($n = 100$) analyzed with the HemoCue instrument ($R^2 = 0.999$). The total coefficient of variation calculated on duplicate samples was 3.9%. There was good agreement between the urine albumin methods (Fig. 1). In general, the Prospec gave slightly higher values. There were 555 samples with urine albumin <20 mg/l on the HemoCue. Nineteen of these samples showed values >20 mg/l on the ProSpec, and of these, only 4 were >25 mg/l. The correlation in the 10- to 150-mg/l range ($n = 184$) was also good ($R^2 = 0.956$). There was also a strong correlation between urine albumin and ACR ($R^2 = 0.937$). A total of 147 (20.7%) of the tested male subjects had urine albumin >20 mg/l and 130 (18.4%) urine albumin >25 mg/l with the HemoCue instrument. One hundred fifty-two (21.5%) of the tested male subjects had ACR >2.5 mg/mmol creatinine and 139 (19.7%) ACR >3 mg/mmol creatinine.

CONCLUSIONS

— Screening for microalbuminuria is usually performed by one of following methods: measurement of total urine albumin in a 12- or 24-h collection, measurement of the ACR in morning urine or random sample, or measurement of urine albumin in morning urine (9). Urine albumin concentrations are standardized for concurrent creatinine excretion, thus obtaining ACR. Repeated measurements have shown that albuminuria is twice as variable as creatininuria (10). However, ACRs often do not take into account diet, sex differences, or the effect of reduced muscle mass, especially in elderly patients. The analytical quality of the creatinine method will influence ACR, and there is also an economical aspect of the question, as ACR requires an additional urine creatinine analysis.

There was a good agreement between the HemoCue and ProSpec quantification of urine albumin, especially considering that presently there is no international calibrator for urine albumin.

In conclusion, the assay presented

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Received for publication 13 June 2005 and accepted in revised form 17 October 2005.

Abbreviations: ACR, albumin-to-creatinine ratio; POCT, point-of-care testing.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

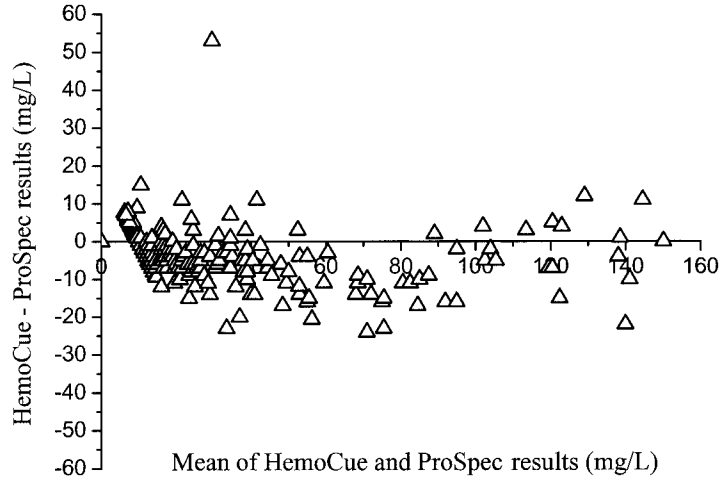

Figure 1—*Bland-Altman plot showing correlation between urine albumin analyzed with the HemoCue and Prospec analyzers in the 10- to 150-mg/l range.*

here is well suitable for microalbuminuria POCT in diabetic patients. The assay is easy to perform and provides results comparable to those of an existing laboratory immunoassay. This study shows a good correlation between urine albumin analyzed with the HemoCue POCT instrument, a central laboratory instrument (ProSpec), and ACR in a group of elderly men. The rapid and quantitative test results obtained directly from urine samples permit clinical decisions to be made at the time of the patient's clinical visit.

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